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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,481	09/29/2000	Sultan Ahmad	81823/273963	7798
7590	03/09/2004		EXAMINER	
Michael A Sanzo Fitch Even Tabin & Flannery 1801 K Street N W Suite 401L Washington, DC 20006-1201			CHERNYSHEV, OLGA N	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/647,481	AHMAD ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 February 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,6-9 and 11-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,6-9 and 11-13 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Response to Amendment

1. Claims 1 and 6 have been amended and claim 10 has been cancelled as requested in the amendment of Paper filed on February 20, 2004. Claims 1, 2, 6-9 and 11-13 are pending in the instant application.

Claims 1, 2, 6-9 and 11-13 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on February 20, 2004 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

5. Claims 1-2, 6-9 and 11-13 stand rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in section 4 of Paper mailed on November 21, 2003. Briefly, the instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

Applicant traverses the rejection on the premises that “the present application asserts that the B1C3 receptor may be used in assays for the purpose of identifying new analgesic drug candidates” (bottom at page 6 of the Response). Applicant refers to the test for credibility as set forth in MPEP (beginning at page 7) and summarizes that based on the evidence presented in the instant specification “it is therefore reasonable to conclude that the B1C3 receptor is probably involved in pain signaling” (middle at page 7). These arguments have been fully considered but are not deemed to be persuasive for the following reasons.

Applicant’s attention is directed to section (b) of the quote of MPEP § 2107.01 presented at the beginning of page 7 of the Response, which reads “the facts upon which the assertion is based are inconsistent with logic underlying the assertion”. The Examiner maintains the position that the instant specification, as filed, fails to provide any factual evidence or sound scientific reasoning that would support an assertion that the instant claimed B1C3 is associated with any specific biological function, including pain. One of ordinary skill in the art readily recognizes the novel B1C3 of the instant invention probably is a G protein-coupled receptor (GPCR) based on its characteristic structure. It is well known in the art that “G protein-coupled receptors located in the central nervous system are known to be involved in the transmission, modulation and sensation of pain” (second paragraph at page 7 of the Response). It is also very well recognized in the art that GPCRs represent the largest family of transmembrane receptors responsible for the transduction of diverse array of extracellular signals, which results in mediation of a variety of intracellular responses that regulate cell function. The instant specification does not provide any basis for concluding that novel B1C3 is particularly associated with nociceptive transduction. Therefore, because the assertion that B1C3 is specifically involved in pain signaling is not

supported by any facts of record, one would reasonably conclude that at the time of filing the biological role of “orphan GPCR” B1C3 was unknown and, further, that the claimed invention is incomplete, therefore, it does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

6. Claims 1-2, 6-9 and 11-13 also stand rejected under 35 U.S.C. 112, first paragraph for reasons of record in section 5 of Paper submitted on November 21, 2003. Briefly, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

7. Claims 1-2, 6-9 and 11-13 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for those reasons of record in section 6 of Paper submitted on November 21, 2003.

Applicant argues that “the genus of polypeptides has been clearly defined” and, further, that “Applicant’s claims only encompass B1C3 and proteins with insubstantial changes”. Applicant also submits that, similarly, the instant claims containing recitation “consisting essentially of” are fully enabled for the use of full scope of recited sequences (page 8 and top at page 9 of the Response). These arguments have been fully considered but are not persuasive for the reasons that follow.

According to the instant specification “[t]he term “consisting essentially of” refers to proteins in which the sequence of SEQ ID NO: 1 has undergone additions, deletions or substitutions which do not substantially alter the functional characteristics of the receptor” (last paragraph on page 1). Contrary to Applicant’s statement, the instant specification does not describe the entire genus of the claimed proteins and polynucleotides. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, in view of the given definition of “consisting essentially of”, the claims encompass molecular embodiments, which have little or no similarity with the instant sequences of SEQ ID NO: 1 or SEQ ID NO: 2, which one would not consider as “insubstantial changes”. Furthermore, there is no identification of any particular portion of the structure that must be conserved. Also, because the instant specification clearly fails to identify specific function of B1C3, a skilled artisan would not know what “functional characteristics of the receptor” are intended to be conserved to meet the limitations of the instant claims. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of

ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides and polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF’s were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. Similarly the instant specification is not enabling because one can not follow the guidance presented therein and practice the claimed invention without first making the substantial inventive contribution at determining which amino acids in SEQ ID NO: 1 are critical to the functional and structural integrity of B1C3 receptor and which amino acids are expendable.

Conclusion

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

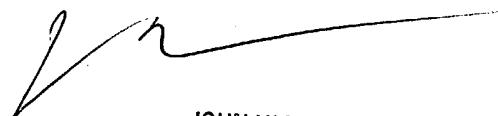
Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original

signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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